during month prior to Run-in
ID#_____
Date __ __/__ __/__ __ __ __

Eligibility Review

NAME:_____
(First) (Last)

Please review and answer all of the questions on this form. We are aware that you have answered these questions within the last several months. However, we need updated answers to these questions before you begin run-in feeding.

Thanks very much for your cooperation.

	Yes	No	Unsure	Comments
1. Have you ever had any of the following?				
a. Stroke	☐ 1	☐ 2	☐ 3	_____
b. Heart attack	☐ 1	☐ 2	☐ 3	_____
c. Heart failure	☐ 1	☐ 2	☐ 3	_____
d. Angina	☐ 1	☐ 2	☐ 3	_____
e. Coronary bypass surgery or angioplasty	☐ 1	☐ 2	☐ 3	_____
f. Prescription for nitroglycerin tablets for heart pain	☐ 1	☐ 2	☐ 3	_____
2. Do you have asthma or another chronic obstructive lung disease, such as chronic bronchitis, emphysema or COPD, etc.?	☐ 1	☐ 2	☐ 3	_____
If yes, within the past 6 months have you: a. Changed breathing medications or increased the dosage of your breathing medication?	☐ 1	☐ 2	☐ 3	_____
b. Been to the emergency room or been hospitalized for breathing problems?	☐ 1	☐ 2	☐ 3	_____
3 Have you ever had cancer?	☐ 1	☐ 2	☐ 3	_____
If yes, was it: Active within the past 6 months or treated with radiation or chemotherapy within the past 6 months?	☐ 1	☐ 2	☐ 3	_____

ID #_____

	Yes	No	Unsure	Comments
4. Have you ever had any of the following stomach or gastrointestinal (GI) conditions?				
a. Chronic GI disorder (such as Inflammatory Bowel Disease, Crohn's Disease, malabsorption)	☐ 1	☐ 2	☐ 3	_____
b. Colostomy or history of bowel resection (removal)	☐ 1	☐ 2	☐ 3	_____
5. Have you ever had kidney failure, a kidney transplant, or dialysis?	☐ 1	☐ 2	☐ 3	_____
6. Do you have any medical conditions or special dietary requirements that might interfere with your ability to eat study foods or attend the clinic for at least one meal a day five days each week?	☐ 1	☐ 2	☐ 3	_____
7. Do you regularly take any of the following?				
a. Tums	☐ 1	☐ 2	☐ 3	_____
b. Rolaids	☐ 1	☐ 2	☐ 3	_____
c. Other non-prescription antacid	☐ 1	☐ 2	☐ 3	_____
d. Vitamins	☐ 1	☐ 2	☐ 3	_____
e. Calcium, magnesium or potassium supplements	☐ 1	☐ 2	☐ 3	_____
f. Salt substitutes	☐ 1	☐ 2	☐ 3	_____
g. Over the counter products or medications containing sodium (see attached list)	☐ 1	☐ 2	☐ 3	_____
h. Metamucil	☐ 1	☐ 2	☐ 3	_____
8. *If you checked yes next to any of the medicines in question 7*, would you be willing to stop taking them during the study?	☐ 1	☐ 2	☐ 3	_____
9. Have you taken any medications to control your blood pressure in the past 3 months?	☐ 1	☐ 2	☐ 3	_____

ID#_____

	Yes	No	Unsure	Comments
10. Do you regularly take any of the following medications?				
a. Steroid or corticosteroid pills	☐ 1	☐ 2	☐ 3	_____
b. Cholestyramine or colestipol	☐ 1	☐ 2	☐ 3	_____
c. Breathing medicines other than inhalers	☐ 1	☐ 2	☐ 3	_____
d. Dilantin or phenytoin	☐ 1	☐ 2	☐ 3	_____
e. Digitalis	☐ 1	☐ 2	☐ 3	_____
f. Lithium	☐ 1	☐ 2	☐ 3	_____
g. Insulin	☐ 1	☐ 2	☐ 3	_____
h. Diet pills/weight loss medication (see attached list)	☐ 1	☐ 2	☐ 3	_____
11. Do you regularly take medications for psychological or emotional problems?	☐ 1	☐ 2	☐ 3	_____
If yes, have you changed medications or the dosage of the medications you take within the past 6 months?	☐ 1	☐ 2	☐ 3	_____
12. Do you currently use smokeless tobacco products (e.g. chew, snuff)?	☐ 1	☐ 2	☐ 3	_____
13. Are you currently taking any lipid lowering medications? (see attached list)	☐ 1	☐ 2	☐ 3	_____
If yes, have you changed your dosage in the past month?	☐ 1	☐ 2	☐ 3	_____
14. Are you planning to leave the area within the next year?	☐ 1	☐ 2	☐ 3	_____

15. On average, how many drinks of alcohol do you have in a week?
If you don't drink alcohol, enter 0.
(one drink = 1 can of beer or 1 glass of wine or 1 shot of liquor)

_____ drinks per week

For women only

16. Are you pregnant, planning to become pregnant or breast feeding?	☐ 1	☐ 2	☐ 3	_____

Reviewed by (staff ID): _____
Entered by (staff ID):_____

Over-the-Counter Drugs and Products Containing Sodium (Question 7, part g)

Baking soda toothpaste
Baking soda for upset stomach
Alka Seltzer
Bisodol powder
Bromo-seltzer

Weight-loss Drugs (Question 10, part h)

This list includes some but not all the over the counter products found in drug stores or health food stores. Please respond yes if you use any product for this purpose.

Generic name	Brand name
Benzphetamine	Didrex
dexfenfluramine	Redux
diethylpropion	Tenuate
	Tepanil
fenfluramine	Pondimin
phentermine	Adipex, Fastin, Ionamin, Obenix, Oby-Cap, Oby-Trim Pro-Fast, Zantril
fenfluramine/phentermine	Fen/Phen
mazindol	Sanorex
	Mazanor
phendimetrazine	Plegine, X-trozine, Bontril, Prelu-2
phenmetrazine	Preludin
phenylpropanolamine	Dexatrim, Accutrim
d-amphetamine	Dexadrine, Dextrostat
methamphetamine	Desoxyn
orlistat	Xenical
sibutramine	Meridia

Lipid-lowering drugs that are exclusionary only if the dosage has changed(Question 13)

Generic name	Brand name
lovostatin	Mevacor
pravastatin	Pravachol
simvastatin	Zocor
fluvastatin	Lescol
atorvastatin	Lipitor
nicotinic acid	Niacin, Slo-Niacin, Niacor, Nicobid, Niacinamide, Nicotinamide
gemfibrozil	Lopid
clofibrate	Atromid-S
bizafibrate	Bezalip
dextrothyroxine sodium	Choloxin
probucol	Lorelco

Administration and Coding Instructions for Medical Eligibility Review

General Coding Instructions

1) Use correct version of form. The correct version will always be on the file server.
2) Use either black or blue pen on all forms, not pencil.
3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data..
6) Do not obliterate or erase any entry of the respondent.
7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, along side the corrected entry, write your initials, the date of the correction and a note about why the correction was made. (e.g., RL, 7/30/97, incorrect ID)
8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
9) Check all lead-in questions for correct skip patterns.
10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered..

Eligibility Review

This review continues the process of screening applicants for a variety of medical conditions and personal habits that would make participants ineligible. Some of these conditions/habits could interfere with the study by obscuring the effects of the study diet. Others might make it harmful or unwise for an individual to participate. The following information is intended to help you assist applicants in providing accurate answers to these questions. When uncertainty remains after reviewing a question with these instructions, please indicate this on the questionnaire so that further review may be undertaken by a study clinician. This review is mainly intended to catch any new medications that participants may be taking and also follow up on any medications/supplements that participants had agreed to stop taking.

Ultimately, all "Unsure" responses must be resolved and coded either "Yes" or "No".

This form will be completed by the participant during the month prior to Run-in <u>if more than 1 month has elapsed</u> since the eligibility questionnaire (form #6) was completed.

Participant and Visit Identifying Data

ID # - Neatly place the label for the ID number that has been assigned on the line, and check to make sure the numbers and letters have been copied correctly. The ID should have five alpha characters and five numerical digits. The alpha characters can be

replaced by asterisks if there are not enough characters in the participant's name (e.g. ABCD*12345). If the letters in the ID # do not match the name of the participant, something is wrong and will need to be corrected before going further.

Date - Clearly enter the date when this form **is reviewed with the participant**. As appropriate, use leading zeros for numbers less than 10 (08/14/1994 represents the date of August 14, 1994).

Q1a-f. These questions are intended to screen for cardiovascular disease other than hypertension. An individual with only hypertension should answer No to each question.

If any question is answered Yes, participant is ineligible for the study.

Q2. This question is intended to screen for individuals with obstructive airways disease that is unstable and thus could interfere with the study. A person who is currently being treated for asthma or COPD, or who has been treated for one of these conditions as an adult, should answer Yes. If an individual has a history of childhood asthma only, with no recurrences as an adult, they may answer No and skip to question 3. If Yes or uncertain, proceed to second part of question.

The second part of this question refers to the past six months. It is important to find out if there has been a worsening in the individual's asthma or COPD, and that should guide the answers to these questions. Any change in medication, including an increase in dose, should be noted as a Yes for Q2a. A decrease in dose of a regular medication, if no other changes have been made, is not significant and should be answered as No. A refill does not constitute a change in medication.

An asthmatic or COPD episode that resulted in a visit in the last six months to the emergency room, urgent/immediate care clinic, or an admission to the hospital should be noted as a Yes to Q2b.

If Yes to either Q2a or Q2b, participant is ineligible.

Q3. Answer Yes to initial inquiry if a person has ever had a diagnosis of cancer. If there is no history of cancer, answer No and skip to question 4.

Inactive cancers are those which have (1) been in remission for over six months or were removed over six months ago AND (2) have not resulted in any further treatment within the past six months. Active cancers include those that have been present within the past six months OR which have required treatment within the past six months. For instance, a woman with breast cancer who had the tumor removed eight months ago, but who was treated with chemotherapy that ended four months ago, would answer Yes to the question "was (your cancer) active in the past six months?"

If Yes to the second part of question 3, participant is ineligible.

Q4. This question is intended to ascertain the presence of a chronic GI disorder that could interfere with bowel function (absorption, fluid and mineral balance). Acute infectious disorders are not of significance and need not be noted (answer No if no other problems present).

The "chronic GI disorders" of interest include those listed and any other that could interfere with bowel function. Answer Unsure if a question arises as to the significance of a condition not listed and refer it to a study clinician after the visit.

Surgery that could influence absorption or fluid and mineral balance should be indicated by answering Yes to the question about colostomy or bowel resection. Minor surgery, such as polyp removal, localized removal of a portion of the colon, or hemorrhoidectomy, is not important. An individual with these minor procedures but no other surgery may answer No.

If yes to either Q4a or Q4b, participant is ineligible.

Q5. This question is for documentation purposes only.

Q6. If Uncertain, list condition in comment field and refer to a study clinician after the visit.

If Yes, the participant is ineligible.

Q7-8. If yes to any item in a - h, Q8 should be answered.

If Q8 is answered No, participant is ineligible.

Q9. If the participant has taken blood pressure medications within the past three months, this question should be answered Yes. If so, the participant is ineligible to continue. Note: participants should be off BP medications for 3 months prior to SV1. This should have been dealt with at SV1 or SV2 when administering the eligibility questionnaire.

Q10. If Yes to any of items a - h, participant is ineligible. If the answer to h (diet pills/weight loss medications), the participant may be screened for a subsequent cohort if they go off the medication. Note: participants should be off weight loss medications 21 days prior to SV1. This should have been dealt with at SV1 or SV2 when administering the eligibility questionnaire.

Q11. This question is intended to identify individuals who are taking unstable doses of psychotropics and/or phenothiazines. If Q11 is answered Yes, ask the second part of the question. Note: participants should have been on a stable dose of psychotropics for 6 months prior to SV1. This should have been dealt with at SV1 or SV2 when administering the eligibility questionnaire.

If Yes to the second part of Q11, participant is ineligible.

Q12. If Yes, participant is ineligible.

Q13. This question is intended to identify individuals who are taking unstable doses of otherwise permissible lipid lowering medications. If Q13 is answered Yes, ask the second part of the question. Note: participants should have been on a stable dose of otherwise permissible lipid lowering medications for one month prior to SV1. This should have been dealt with at SV1 or SV2 when administering the eligibility questionnaire.

If Yes to the second part of Q13, participant is ineligible.

Q14. If Yes, participant is ineligible.

Q15. If participant consumes 15 or more drinks per week, he/she is ineligible. Participants who do not drink alcohol should enter zero.

Q16. This is completed only by women. If Yes, participant is ineligible.

Reviewed by - Record the Staff ID # of the person reviewing the form.

Entered by. - Record the Staff ID # of the person entering the data in the computer.

If any of the shaded boxes on this form are checked, the participant is ineligible.